For Immediate Release

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ENZI SAYS TIME IS NOW FOR CONGRESS TO ACT ON ENZI-KENNEDY DRUG SAFETY BILL

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee, today said the time is ripe for Congress to act on a bill that will restore public confidence in the Food and Drug Administration (FDA). The Enzi-Kennedy legislation would require drug makers to engage in better safety planning before a drug is approved for release to the public, and improve the FDA's response to risks identified after a drug is on the market.

"The 'Enhancing Drug Safety and Innovation Act,' S. 3807, will raise the bar to ensure that drug safety is not an afterthought, but an integral part of the process from the very beginning," Enzi said. "This bipartisan bill is designed to provide better, flexible, adaptive, and rapid safeguards to protect the millions of Americans who take prescription drugs daily."

"When new information comes to light that demonstrates previously unknown risks about a drug, the FDA, together with the drug industry and physicians, must be ready and able to take swift, appropriate, and decisive action to ensure patient safety," Enzi added.

Enzi chaired a hearing today, "Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation," to focus on the need to encourage the development of new technologies and new techniques at the FDA, so that it can do its job: develop new and more efficient ways to evaluate and predict the safety of new drugs before they enter widespread use.

Enzi and the Committee's Ranking Member, Senator Edward Kennedy (D-MA) have spent nearly two years developing the proposal in hopes of restoring public confidence in the FDA's review process for prescription drugs. A recent report issued by the Institute of Medicine (IOM), makes recommendations similar to

many provisions found in the Enzi-Kennedy bill. The IOM’s recommendations and the Enzi-Kennedy bill include giving FDA the authority to: make label changes, order post-market studies, restrict Direct To Consumer Advertising, and restrict distribution of drugs.

Enzi said the bill, which reflects the comments and input of dozens of stakeholders, including the FDA, patient and consumer groups, industry trade associations, individual companies, and scientific experts, will:

* Integrate safety issues and the approval process by requiring earlier and more focused consideration of safety issues;

* Establish a flexible planning mechanism to obtain the necessary safety information about each unique new drug or indication;

* Permit adaptation of the safety plan in response to new information; and,

* Bring fairness, timeliness and finality to the dispute resolution process.

Other key provisions of the bill include:

* Establishing a collaboration among the FDA, academic research institutions, and the biomedical research industry to improve the process of drug development and evaluation, and advance the FDA's Critical Path Initiative;

* Establishing a publicly available database of clinical trials to help enhance patient enrollment in clinical trials of drugs, provide a mechanism to track subsequent progress of trials, and ensure that the results of trials are made public, and that patients, doctors, and pharmacists have the most up-to-date information;

* Making improvements to the FDA’s process of screening advisory committee members for financial conflicts of interest to ensure that these committees provide independent expert advice, and to bolster the credibility of the product review process.

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